The Institutional Review Board (IRB) of the Virginia Department of Health (VDH):

Standard Operating Procedures and Guidelines for Obtaining Review

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Commissioner

VDH VIRGINIA DEPARTMENT OF HEALTH
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I. GUIDELINES FOR OBTAINING REVIEW BY THE INSTITUTIONAL REVIEW BOARD (IRB) OF THE VIRGINIA DEPARTMENT OF HEALTH (VDH)

A. Introduction

One of the many ways the Virginia Department of Health (VDH) serves the public and fulfills its mission is through research. Research is defined in federal regulations as a *systematic investigation designed to develop or contribute to generalizable knowledge*. Periodically VDH conducts research that involves human subjects. VDH considers the protection of human subjects as important as the methodology, research findings, or any other component of the research project.

VDH has developed policies and procedures to ensure that the rights and welfare of human subjects involved in research are protected and consistent with both State (12 VAC 5-20-10) and Federal (45 CFR Part 46) regulations. The Office for Human Research Protections (OHRP), under the U.S. Department of Health and Human Services Assistant (HHS) Secretary for Health, is responsible for ensuring the safety and welfare of people who participate in HHS-sponsored research. Policies, guidelines and regulations from OHRP, including the ethical principles found in the Belmont Report, provided the framework for the development of the State regulations, and provide the structure for VDH review and approval of human subjects research.

A major component of the process for ensuring the protection of the rights and welfare of human subjects involved in VDH research is the Institutional Review Board (IRB), also known as the research review committee. Research protocols must be either approved or granted an exemption by the IRB before human subjects can begin participation. The IRB also conducts continuing review of each approved protocol at least annually. The IRB may modify, suspend or terminate approval of research that has been associated with serious harm to subjects or is not being conducted in accord with the IRB's decisions, stipulations, and requirements.

The purpose of this document is to assist researchers and managers with determining whether a particular project requires review by the IRB, and if so, which of the various types of review is required. Additionally, this document outlines the actual processes and procedures needed for obtaining review by the IRB. Finally, this document also contains the text of the state regulations concerning the conduct of human research for VDH and a reproducible copy of all forms needed for obtaining review by the IRB.

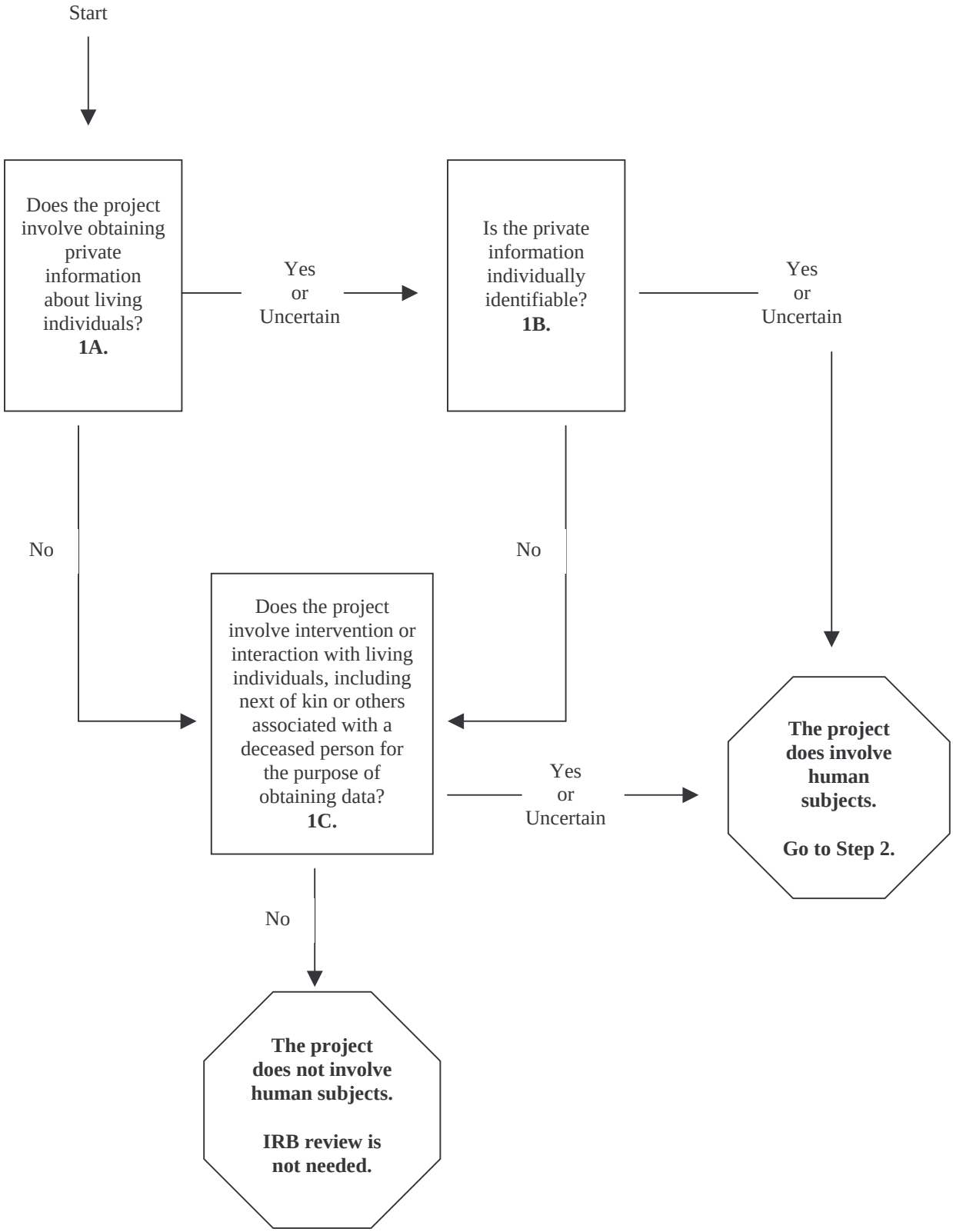
B. Key Decisions about Human Subjects Review Requirements

In general, any research that is conducted by VDH, by outside investigators in collaboration with VDH, or by outside investigators using VDH data, is subject to review and approval by the VDH Institutional Review Board (IRB). However, not all studies require IRB review. This section covers the process for determining the need for IRB review. The decision-making process is divided into four key decision steps:

Step 1: Does the project involve human subjects?
Step 2: Is the project considered research?
Step 3: Does the project qualify for exemption review?
Step 4: Does the project qualify for expedited review?

Each step is outlined in a flow diagram that is followed by a description.

STEP 1: DOES THE PROJECT INVOLVE HUMAN SUBJECTS?*



*Please consult complete descriptions on the following page

STEP 1: DOES THE PROJECT INVOLVE HUMAN SUBJECTS?

The VDH investigator and/or VDH staff responsible for the data should determine whether the project involves human subjects.

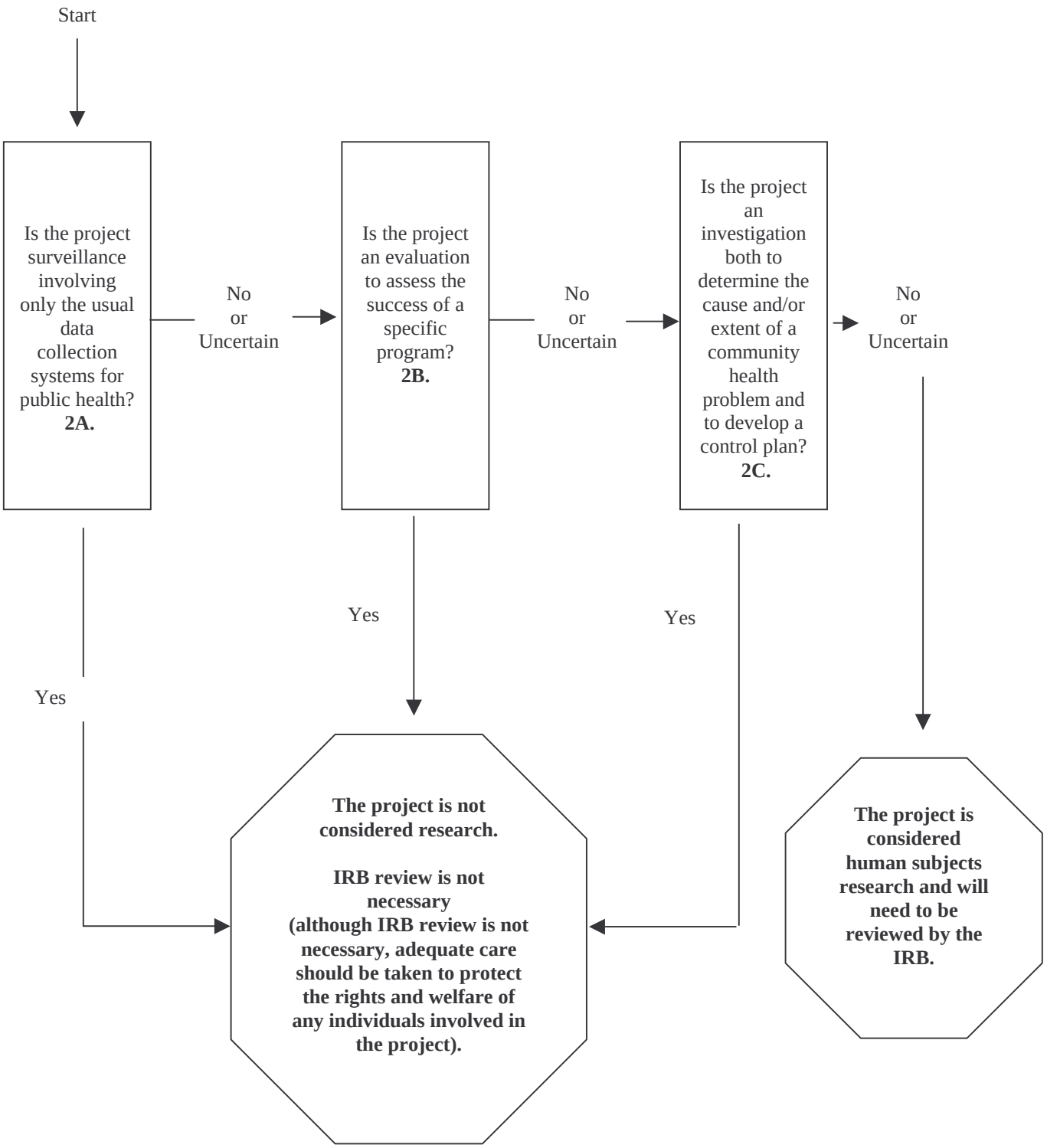
1A. Does the Project Involve Obtaining Private Information About Living Individuals?
Private information is defined as (1) information which has been provided for specific purposes by an individual which (s)he can reasonably expect will not be made public (e.g., a medical record), or (2) information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.

1B. Is the Private Information Individually Identifiable?
Individually identifiable means that private information is recorded in such a way that (1) the identity of the subject is or may be ascertained by the investigator, or (2) the identity of the subject may readily be inferred from the information obtained.

1C. Does the Project Involve Intervention or Interaction with Living Individuals for the Purpose of Obtaining Data?
Intervention includes physical procedures by which data are collected, such as venipuncture, and manipulations of the subject or the subject's environment. Interaction includes communication or interpersonal contact with the subject, the subject's next of kin, or the subject's physician or hospital.

If you responded in the affirmative to **ANY ONE** of the above three questions, then you need to proceed to Step 2. If you responded in the negative to **ALL THREE** of the above questions, then your project does not involve human subjects and will not need to be reviewed by the IRB.

STEP 2: IS THE PROJECT RESEARCH?*



*Please consult complete descriptions on the following pages

STEP 2: IS THE PROJECT RESEARCH?

If the project involves human subjects, the VDH investigator should then determine whether the project constitutes research (a systematic investigation designed to develop or contribute to generalizable knowledge). The main criterion for determining whether a project is research is the purpose of the activity. The project is research if its primary purpose is to gain knowledge that is generalizable to other populations and/or other settings. Examples of research projects include studies of the effects of behavior modification strategies on health outcomes, surveys of health care behaviors and practices in a sample of the population, and studies of exposed and unexposed populations living near hazardous waste sites. In contrast, the project is *not* research if it is primarily being conducted to gain knowledge and information that can be immediately used to benefit the participants. Note that if at any point the purpose of the project changes so that the project becomes a systematic investigation designed to develop or contribute to generalizable knowledge, the investigator must consult the IRB to determine the need for review.

2A. Is the Project Surveillance Involving Only the Usual Data Collection Systems for Public Health?

Surveillance refers to the regular ongoing collection and analysis of health-related data (in terms of time, place, person). If the surveillance activity is conducted solely to monitor the frequency of occurrence and distribution of disease or health condition in the population, it is not considered research. Such activities are the public health equivalent of a private physician checking the vital signs of an individual patient. According to state regulations, the surveillance and investigation by VDH into all preventable diseases and epidemics in the Commonwealth and into the means for the prevention of such diseases and epidemics conducted pursuant to §32.1-39 of the Code of Virginia are not considered research and thus exempt from IRB review.

If, on the other hand, surveillance activity is being conducted, *in whole or in part*, to gather data and obtain knowledge from which to generalize to other populations and/or settings, the project is considered research. An example is a study for the purpose of determining why certain groups are at higher risk of disease than others.

2B. Is the Project an Evaluation to Assess the Success of a Specific Program?

Evaluations of ongoing public health programs may or may not constitute research. A program evaluation is not considered research if the purpose of the evaluation is to assess the success of a specific program in achieving its objectives and is part of normal public health program operations, analogous to the ongoing monitoring by surgeons of their patients so that corrective action can be taken to improve the quality, effectiveness, and cost-effectiveness of the care they provide. If, on the other hand, the purpose of a program evaluation is to develop or contribute to generalized knowledge, the project is considered research. However, some evaluation research may qualify for exemption review (see Step 3).

2C. Is the Project an Investigation Both to Determine the Cause and/or Extent of a Particular Community Health Problem and to Develop Plans for its Control?

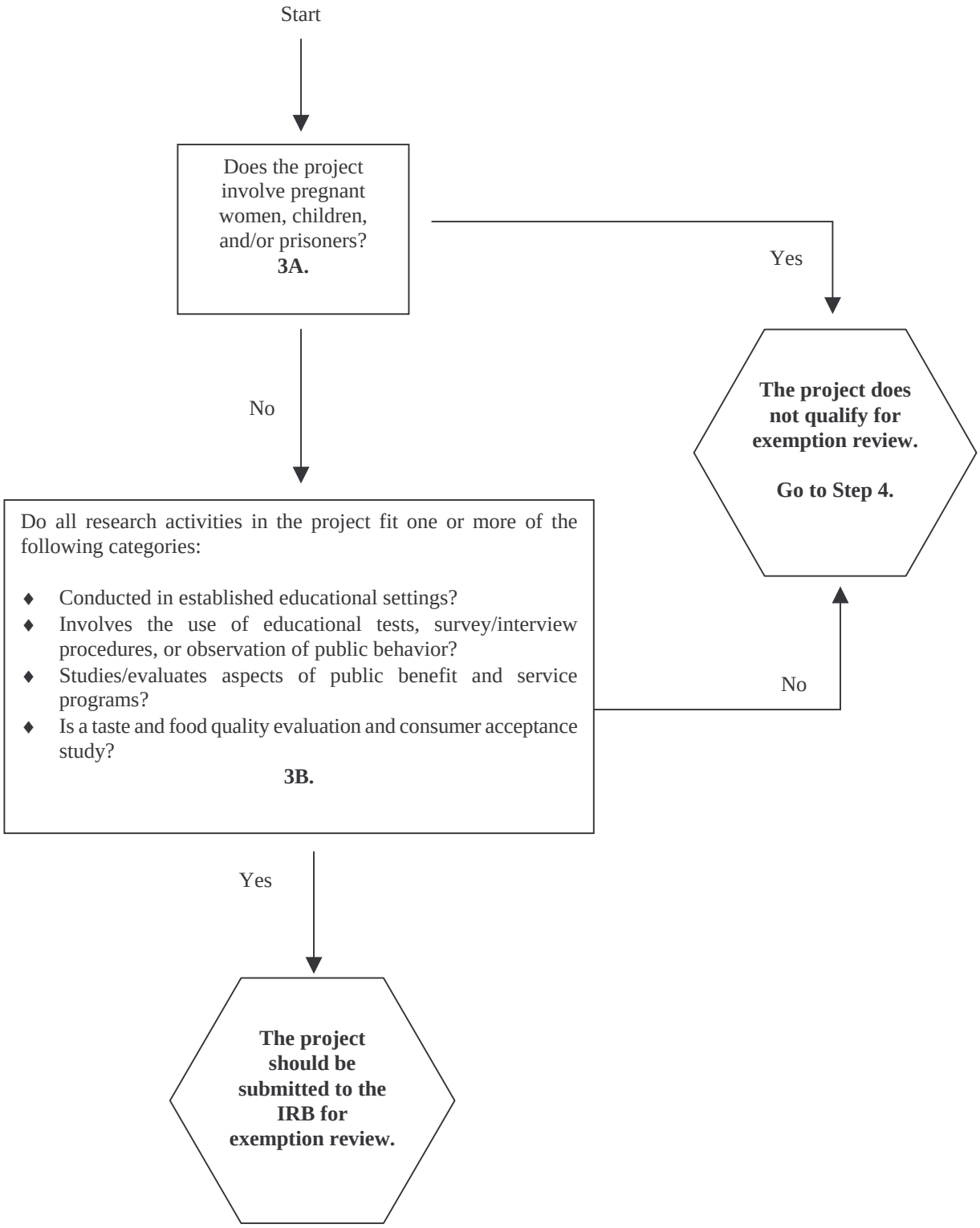
OHRP regulations specify that the regulations are not intended to interfere with the ability of a physician to provide emergency medical care. It logically follows that the regulations must not impair the ability of VDH staff and other public health officials to investigate and respond to public health emergencies. When responding to a public health emergency, VDH considers such investigations as the public health equivalent of individual doctor-patient situations in which the community (as patient) presents with a health problem, which VDH and other health agencies (as physician) are expected to diagnose and control (treat) without delay. Additionally, state regulations specify that the investigation by the department into all preventable diseases and epidemics in the Commonwealth and into the means for the prevention of such diseases and epidemics conducted pursuant to the *Code* are not bound by regulations concerning research. Thus, an investigation is *not* research if its primary purpose is to determine the cause and/or extent of a community health problem and to develop plans for its control.

Specific examples of nonresearch investigations include the prompt investigation of an outbreak of gastrointestinal illness in a community or an investigation of the exposure of a group of people to a cloud of toxic gas. These nonresearch investigations may include interviews with affected or potentially affected subjects to obtain medical histories, medical and health records reviews, physical examinations, and routine medical tests (e.g., blood tests, chest radiographs, and electrocardiograms) to determine the existence and nature of their health problems.

If you responded in the affirmative to **ANY ONE** of the above three questions, then the project is not considered research and IRB review is not necessary. However, adequate care should still be taken to protect the rights and welfare of any individuals involved in the project. For example, if the project involves obtaining private, individually identifiable information about living individuals to obtain data, measures should be taken which will ensure protection of those individuals. Potential participants in a project should know that their participation is voluntary before they are asked questions or specimens are taken from them. Investigators should also consider whether the use of consent forms would help protect human subjects. The IRB is always available to provide guidance for determining if IRB review is required. Even if IRB review is not required, the project may still request IRB review to address ethical questions posed by the investigator or reviewers, or because of potential controversy or publicity associated with the project.

If you responded in the negative (or with uncertainty) to **ALL THREE** of the above questions, then you will need to submit your research protocol to the IRB for review. You should proceed to Step 3 to determine if your protocol should be submitted for exemption review, expedited review, or full board review.

STEP 3: DOES THE PROJECT QUALIFY FOR EXEMPTION REVIEW?*



*Please consult complete descriptions on the following pages

STEP 3: DOES THE PROJECT QUALIFY FOR EXEMPTION REVIEW?

Certain research activities involving human subjects have been given exemptions from IRB full board review through either federal and/or state regulations. If an investigator feels that the research activities being proposed fall into one of the exemption categories, those protocols should be submitted to the IRB for exemption review (see previous page for flow diagram). The decision to approve or disapprove a project submitted for exemption review will be made by the Chair of the IRB or his/her designee and one additional member of the review board. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission. The purpose of the exemption review process is to provide assurance that a particular research project does indeed meet the criteria for exemption. *All* of the research activities in a project that involve human subjects must be exempt in order for the project to be submitted for exemption review. If only one activity is not exempt, the project is not exempt.

3A. Does the project involve pregnant women, children, or prisoners?

Pregnant women, children (persons who have not attained the legal age for consent to treatments or procedures involved in the research) or prisoners are considered vulnerable populations. Any project involving vulnerable populations must undergo either expedited or full board review and does **not** qualify for exemption review.

3B. Do ALL research activities in the project fit one or more of the following categories?

If all research activities in the project fit one ore more of the following five categories, then that research project may qualify for exemption review. Please read these categories carefully, as some contain rule exceptions.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies; or research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods qualifies for exemption review.

(2) Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior qualifies for exemption review ***unless****:*

(a) information is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation – this includes, but is not limited to sensitive aspects of the participant's own behavior such as sexual behavior, drug or alcohol use, or illegal conduct.

However, research normally not exempt from IRB review according to criteria (a) and (b) above may be exempt *if*: (a) the human subjects are elected or appointed public health officials or

candidates for public offices *or* (b) Federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(3) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects qualifies for exemption review. This includes research designed to study on a large scale anonymous vital records and registry data collected pursuant to the Code of Virginia, Chapter 7 (§32.1-249 et seq.) of Title 32.1 (Vital Records), §32.1-64.1 (Virginia Hearing Impairment Identification and Monitoring System), §32.1-69.1 (Viginia Congenital Anomalies Reporting and Education System), §32.1-70 (Statewide Cancer Registry), §32.1-71.l (Statewide Alzheimer's Disease and Related Disorders Registry), and §§32.116.1 and 32.116.1:2 (Emergency Medical Services Patient Care Information System).

(4) Research and demonstration projects conducted by VDH or subject to the approval of VDH and designed to study, evaluate or otherwise examine:

(a) public benefit or service programs;

(b) procedures for obtaining benefits or services under those programs;

(c) possible changes in or alternatives to those programs or procedures; or

(d) possible changes in methods or levels of payment for benefits or services under those programs

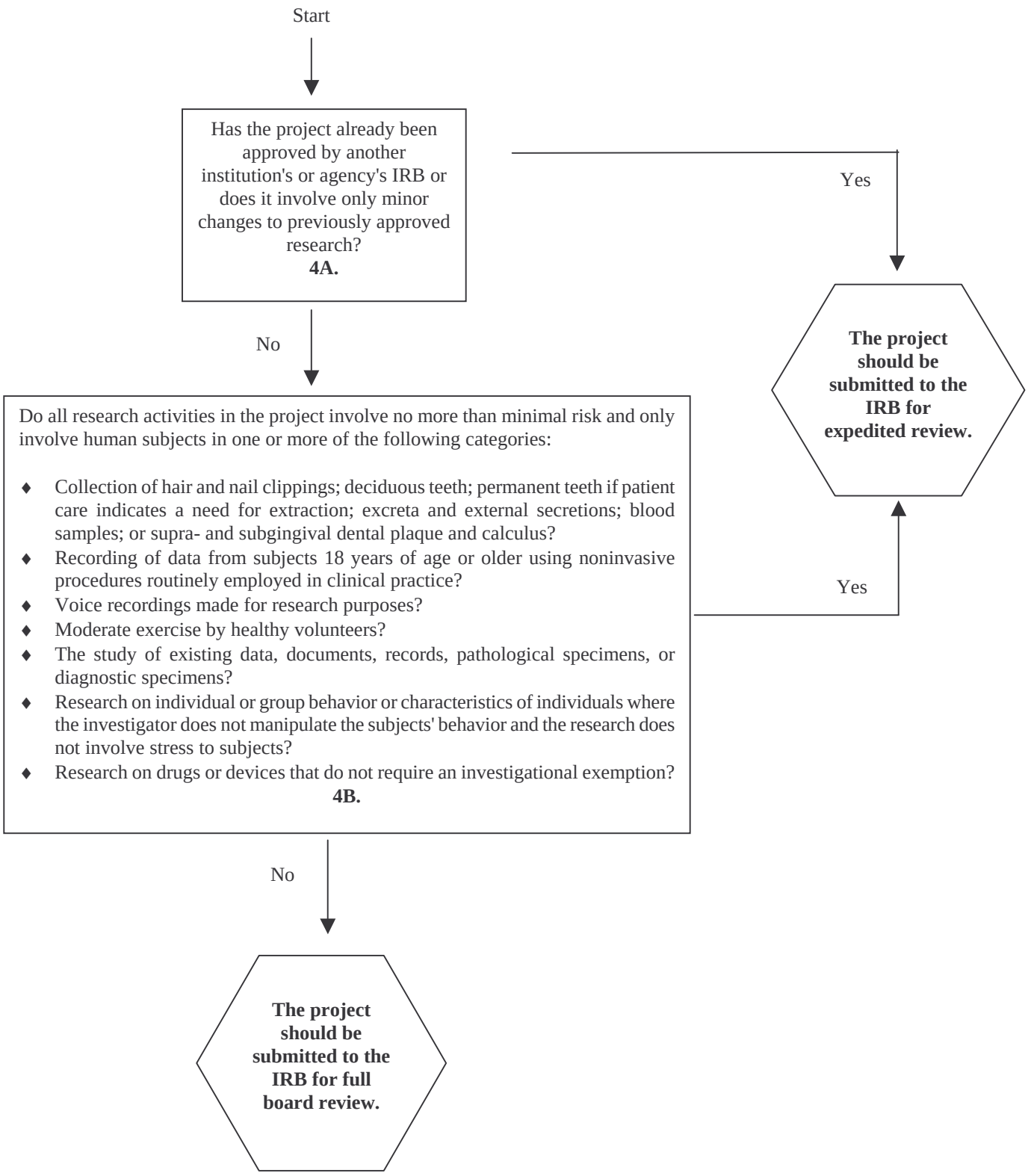
qualify for exemption review.

(5) Taste and food quality and consumer acceptance studies if: (a) wholesome foods without additives are consumed or (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture qualify for exemption review.

If the project does **NOT** involve vulnerable populations **AND** all activities fit into one or more of the above categories, then the investigator should submit the protocol to the IRB for exemption review. Even if the IRB determines that a study is indeed exempt, the investigator may still request a full board review. This might be done to address ethical questions posed by the investigator or reviewers, or it might be done because of potential controversy or publicity associated with the project.

If the project **DOES** involve vulnerable populations and/or all activities **DO NOT** fit into one or more of the above categories, then you should proceed to Step 4 to determine if your protocol would qualify for expedited review or need to be submitted for full board review.

STEP 4: DOES THE PROJECT QUALIFY FOR EXPEDITED REVIEW?*



*Please consult complete descriptions on the following pages

STEP 4: DOES THE PROJECT QUALIFY FOR EXPEDITED REVIEW?

Certain research activities involving human subjects qualify for an expedited review process as a result of either federal and/or state regulations. The decision to approve or disapprove a project submitted for expedited review will be made by the Chair of the IRB or his/her designee and one additional member of the review board. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission.

4A. Has the project already been approved by another institution's or agency's IRB or does it involve only minor changes to previously approved research occurring during the approved project period? State regulations allow research projects that have already been reviewed and approved by the IRB of another institution or agency to undergo expedited review.

4B. Do all research activities in the project involve no more than minimal* risk and only involve human subjects in one or more of the following categories provided by federal regulations for expedited review?

(1) Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

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* "Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research does not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

If the project has been reviewed and approved by another IRB and/or all activities involve no more than minimal risk with human subjects in one or more of the qualifying categories, then the investigator should submit the protocol for expedited review. However, if the project has **NOT** been reviewed by another IRB, **and/or** all activities do **NOT** involve more than minimal risk with human subjects in one or more of the qualifying categories, then the project must be submitted to the IRB for full board review.

Full board review requires attendance of the principal investigator at a meeting of the IRB. The IRB is required by state regulations to review all requests within 45 days after submission. The IRB is scheduled to meet quarterly (January, April, July, October) and will convene more often as needed. In order for research to be approved, it must receive the approval of a majority of those members present at a meeting in which a quorum exists. A quorum consists of a majority of the members, including at least one member whose primary concerns are in a nonscientific area. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the investigator in writing within 7 business days of the IRB meeting where the submission is reviewed.

II. PROCEDURES FOR OBTAINING REVIEW BY THE INSTITUTIONAL REVIEW BOARD (IRB) OF THE VIRGINIA DEPARTMENT OF HEALTH (VDH)

A. Introduction

Researchers and managers who have reviewed the guidelines and have made the determination that a project does indeed involve human subjects and is considered research will need to make a request for IRB review. Requests for IRB review will fall into one of three categories:

(1) Request for Full Board Review;
(2) Request for Expedited Review; or
(3) Request for Exemption from IRB Review.

All requests for review are to be submitted to the Office of Health Policy/Institutional Review Board, VDH. Criteria and procedures for obtaining clearance for each of the specific categories are described in Sections B, C, and D.

1. **General Criteria for IRB Approval of Research:** In order to approve non-exempt research, the IRB will consider the following elements of the proposal:

   a. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research. *Risks to subjects are to be minimized and benefits to subjects maximized by using procedures which are consistent with sound research design*

   b. The degree of risk, and, if the research is nontherapeutic*, whether it presents greater than minimal risk**. *Risks to subjects are to be minimized by using procedures which do not unnecessarily expose the subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.*

   c. The necessity and utility of the research and whether the risks to the subjects are outweighed by the potential benefits of the research and the importance of the knowledge that may reasonably be expected to result. *In evaluating risks and benefits, the IRB will consider only risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks or potential benefits that fall within the purview of its responsibilities.*

   d. The equity in criteria for selection of subjects, especially in research regarding the future development of mental or physical illness**.** *In making this assessment, the IRB will take into*

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* *"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the participant.*

** *Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically/educationally disadvantaged persons.

e. The adequacy of protection of rights and welfare of the participants. These include the following:

- *Voluntary informed consent is sought from each prospective subject or the subjects' legally authorized representative and appropriately documented.*
- *Voluntary informed consent is obtained by methods that are adequate and appropriate to the subject's educational level and language of greatest fluency.*
- *The written consent form is adequate and appropriate in both content and wording for the particular research and for the particular subjects of the research relative to their educational level and language of greatest fluency and reasonably reflects full explanation and adequate understanding.*
- *The person(s) proposed to supervise or conduct the particular research protocol are appropriately competent and qualified.*
- *When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.*
- *When appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data.*
- *When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically/ educationally disadvantaged persons, additional safeguards are included in the study to protect the rights and welfare of these subjects*

2. **General Requirements for Informed Consent:** Informed consent means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to be given before such consent can be attained shall include:

a. a statement that the study involves research; an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures or protocols to be followed, identification of any procedures which are experimental; and where applicable, disclosure of the approximate number of subjects involved in the study;

b. a description of any reasonably foreseeable risks or discomforts to the subject and a statement that there may be other risks not yet identified (e.g.; a statement that the particular treatment or procedure may involve risks to the subject or to the embryo or fetus, if the subject is or may become pregnant, which are currently unforeseeable);

c. a description of any benefits to the subject or to others which may reasonably be expected from the research; and a statement that significant new findings developed during the course of the research which may be related to the subject's willingness to continue participation will be provided to the subject;

d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; and if any data from the study are published, a statement that the subject will not be identified without the subjects written permission;

f. for research involving more than minimal risk*, an explanation as to whether any compensation or medical care is available if injury occurs and, if so, what is included or where further information may be obtained;

g. an explanation of any costs or compensation which may accrue to the subject and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols;

h. an offer to answer any inquiries by the subject concerning the procedures and protocols, and an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

i. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may withdraw his consent and discontinue participation at any time without prejudice;

j. where applicable, a disclosure of the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; and

k. where applicable, any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

a. the research involves no more than minimal risk* to the subjects;

b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;

* "Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

c. the research could not practicably be carried out without the waiver or alteration; and

d. whenever appropriate, the subjects will be provided with additional pertinent information after participation

3. **General Requirements for Documentation of Informed Consent:** Informed consent shall be documented by the use of a written consent form approved by the IRB (a sample consent form is in Appendix C) and signed by the subject or the subject's legally authorized representative with the exception of the following situations:

a. that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

b. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

The consent form may be either a written form that embodies the elements of informed consent or a short-form written document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative and witnessed by a third party. In either case, a copy of the document shall be given to the person signing the form. If oral presentation is being proposed, a written summary of the oral presentation in addition to the short-form written document should be included in the documentation portion of the request for review being made to the IRB.

All forms and documents should be submitted to:
Office of Health Policy and Planning/
Institutional Review Board
Virginia Department of Health
109 Governor Street, 10th Floor East
P.O. Box 2448
Richmond, VA 23218-2448

For questions or additional information, please contact:
Kathy H. Wibberly, Ph.D., Chair of the VDH IRB
Phone: 804-864-7429
Fax: 804-864-7440
E-mail: Kathy.Wibberly@vdh.virginia.gov

B. Requests for Full Board Review

The following is a checklist of documents that must be submitted by the principal investigator in order to obtain full board review and clearance:

- ❑ Request for Review and Clearance of a Project Involving Human Subjects (Appendix D) with requested supporting documentation to include the study protocol (if the study is a part of a larger protocol, such as a cooperative agreement with CDC for public health surveillance/intervention, only submit relevant portions of the protocol) and informed consent form(s). Study protocols should include sections on Hypotheses, Goals of Study, Background and Significance of Study, Preliminary Progress/Data Report (if available), Research Method and Design, and Statistical Analyses Planned (or in progress).

- ❑ Letter(s) and other materials that will be supplied to study subjects

- ❑ Questionnaire(s) (when applicable)

Full Board review requires the submission of 1 electronic OR 7 hard copies of the "Request for Review" application and supporting documents, and requires attendance of the principal investigator at a meeting of the IRB. The IRB is required by state regulations to review all requests within 45 days after submission. The IRB is scheduled to meet quarterly (January, April, July, October) and will convene more often as needed. In order for research to be approved, it must receive the approval of a majority of those members present at a meeting in which a quorum exists. A quorum consists of a majority of the members, including at least one member whose primary concerns are in a nonscientific area. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the investigator in writing within 7 business days of the IRB meeting where the submission is reviewed.

Continuation Review reports are to be submitted at least annually for all approved studies to ensure conformity with the proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. In addition, the IRB will require a study summary report from the investigator at the conclusion of the research project. The Office of Health Policy and Planning/Institutional Review Board will automatically mail out the continuing review report form (Appendix E) to principal investigators just prior to the review due date. The form must be completed and returned for ongoing projects.

Finally, whenever an ongoing project acquires a new principal investigator, or whenever there are substantial changes (e.g., changes in consent procedures, addition of potentially sensitive items to research instruments, changes in treatment procedures) in the protocol or the subject population, another request for IRB review must be filed.

C. Requests for Expedited Review

The following is a checklist of documents that must be submitted by the principal investigator in order to obtain expedited IRB review and clearance:

- ❑ Request for Review and Clearance of a Project Involving Human Subjects (Appendix D) with requested supporting documentation to include the study protocol (if the study is a part of a larger protocol, such as a cooperative agreement with CDC for public health surveillance/intervention, only submit relevant portions of the protocol) and informed consent form(s). Study protocols should include sections on Hypotheses, Goals of Study, Background and Significance of Study, Preliminary Progress/Data Report (if available), Research Method and Design, and Statistical Analyses Planned (or in progress).

- ❑ Letter(s) and other materials that will be supplied to study subjects

- ❑ Questionnaire(s) (when applicable)

- ❑ IRB approval document(s) (if requesting expedited review because the study has been approved by the IRB at another institution or agency)

Expedited review requires the submission of 1 electronic OR 2 hard copies of the "Request for Review" application and supporting documents. The decision to approve or disapprove a project submitted for expedited review will be made by the Chair of the IRB or his/her designee and one additional member of the review board. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission.

Continuation Review reports are to be submitted at least annually for all approved studies to ensure conformity with the proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. In addition, the IRB will require a study summary report from the investigator at the conclusion of the research project. The Office of Health Policy and Planning/Institutional Review Board will automatically mail out the continuing review report form (Appendix E) to principal investigators just prior to the review due date. The form must be completed and returned for ongoing projects.

Finally, whenever an ongoing project acquires a new principal investigator, or whenever there are substantial changes (e.g., changes in consent procedures, addition of potentially sensitive items to research instruments, changes in treatment procedures) in the protocol or the subject population, another request for IRB review must be filed

D. Requests for Exemption from IRB Review

If an investigator believes that their research project qualifies for exemption (see pages 7 - 9), the following is a checklist of documents that must be submitted in order to obtain IRB exemption status:

- ❑ Request for Exemption from IRB Review Form (Appendix F)
- ❑ Cover letter with a detailed written explanation of why the project should be regarded as exempt
- ❑ Study protocol (if the study is a part of a larger protocol, such as a cooperative agreement with CDC for public health surveillance/intervention, only submit relevant portions of the protocol). Study protocols should include sections on Hypotheses, Goals of Study, Background and Significance of Study, Preliminary Progress/Data Report (if available), Research Method and Design, and Statistical Analyses Planned (or in progress).
- ❑ Letter(s) and other materials that will be supplied to study subjects
- ❑ Questionnaire(s) (when applicable)

Exemption review requires the submission of 1 electronic OR 2 hard copies of the "Request for Exemption" application and supporting documents. The decision to approve or disapprove a project submitted for exemption review will be made by the Chair of the IRB or his/her designee and one additional member of the review board. All IRB decisions regarding approval, disapproval, or of required modifications will be communicated to the principal investigator in writing within 15 business days following submission.

APPENDIX A:

THE BELMONT REPORT:

ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH

The National Commission
for the Protection of Human Subjects
of Biomedical and Behavioral Research

April 18, 1979

Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes (1) intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

Part A: Boundaries Between Practice & Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.(2) By contrast, the term "research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine

whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.(3)

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

Part B: Basic Ethical Principles

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. Respect for Persons. -- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence. -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice. -- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to

each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Part C: Applications

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. Informed Consent. -- Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another

standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that **(1)** incomplete disclosure is truly necessary to accomplish the goals of the research, **(2)** there are no undisclosed risks to subjects that are more than minimal, and **(3)** there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited -- for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disable patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitle.

2. Assessment of Risks and Benefits. -- The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

The Nature and Scope of Risks and Benefits. The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.
The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike, "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

The Systematic Assessment of Risks and Benefits. It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations:
(i)
Brutal or inhumane treatment of human subjects is never morally justified. **(ii)** Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. **(iii)** When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation). **(iv)** When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. **(v)** Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. Selection of Subjects. -- Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.
Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular

institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

(1) Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

(2) Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

(3) Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

National Institutes of Health
Bethesda, Maryland 20892

APPENDIX B:

REGULATIONS FOR THE CONDUCT OF HUMAN RESEARCH

COMMONWEALTH OF VIRGINIA
BOARD OF HEALTH
12 VAC 5-20-10

Effective: July 1, 1993

REGULATIONS FOR THE CONDUCT OF HUMAN RESEARCH

PART I: GENERAL PROVISIONS

1.1 Definitions

The following words and terms, when used in these regulations, shall have the following meanings, unless the context clearly indicates otherwise:

"Affiliated with the institution" means employed by or contracting with the institution or directly or indirectly involved in the management thereof.

"Commissioner" means the Commissioner of the Department of Health.

"Committee" means human research committee assembled pursuant to 12VAC5-20-70 of this chapter by any institution defined herein.

"Department" means the Department of Health.

"Human research" means any systematic investigation utilizing human participants who may be exposed to physical or psychological injury as a consequence of participation and which departs from the application of established and accepted therapeutic methods appropriate to meet the participants' needs.

"Informed consent" means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to such consent shall include:

A. A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected;

B. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;

C. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to him;

D. An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols; and

E. An offer to answer any inquiries by any individual concerning the procedures and protocols.

In addition to the required elements, the information provided to the individual should also include the following:

A. A statement that the study involves research, and an explanation that includes identification of any procedures which are experimental; the expected duration of the individual's participation; and a

statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and if any data from this study are published, the individual will not be identified without his written permission;

B. A statement that there may be other risks not yet identified;

C. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;

D. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled;

E. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury; and

F. For research involving more than minimal risk, an explanation as to whether any compensation or medical care is available if injury occurs and, if so, what is included or where further information may be obtained.

Information should be provided in a manner that is understandable to the individual with regard to his educational level and language of greatest fluency.

"Institution" or "agency" means any facility, program, or organization owned or operated by the Commonwealth, by any political subdivision, or by any person, firm, corporation, association, or other legal entity.

"Legally authorized representative" means the parent or parents having custody of a prospective participant, the legal guardian of a prospective participant or any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective participant to such person's participation in the particular human research. For the purposes of this chapter, any person authorized by law or regulation to consent on behalf of a prospective participant to his participation in the particular human research shall include an attorney-in-fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney-in-fact shall not be employed by the person, institution or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the participant.

1.2 Applicability

This chapter shall apply to the department, including any local health department and to any facility operated, funded or licensed by the department which conducts or which proposes to conduct or authorize research which uses human participants.

1.3 Policy

A. No human research may be conducted without informing the participant or his legally authorized representative of the procedures, risks, and discomforts of the research. The consent of the participant or his legally authorized representative to participate in the research shall be subscribed to in writing by the participant or his legally authorized representative and supported by the signature of a witness not involved in the conduct of the research, except as provided for in 12VAC5-20-100 F and H of this chapter. Special arrangements shall be made for those who need assistance in understanding the consequences of participating in the research.

B. Each human research activity shall be reviewed and approved by a committee as set forth in 12VAC5-20-70 of this chapter composed of representatives of varied backgrounds who shall assure the competent, complete, and professional review of human research activities.

C. Every person engaged in the conduct of human research or proposing to conduct human research shall associate himself with an institution or agency having a research review committee, and the human research which he conducts or proposes to conduct shall be subject to review and approval by such committee in the manner set forth in these regulations.

D. Nontherapeutic research using patients or residents within an institution as defined herein is forbidden unless it is determined by the research review committee that such nontherapeutic research will not present greater than minimal risk.

E. The individual conducting the research shall be required to notify all participants of research of the risks caused by the research which are discovered after the research has concluded. If consent has been obtained by the signature of the legally authorized representative, the legally authorized representative shall also be notified.

PART II: THE REVIEW PROCESS

2.1 For the Department

A. Prior to the initiation of a human research project by any component of the department, a description of the proposed human research project shall be submitted to a research review committee established by the department for review and approval. The description shall include a statement of the purpose of the proposed project and justification thereof, the criteria for inclusion of a participant in the research project, a description of what will be done to the participants, and a copy of the informed consent statement.

B. The committee shall report by January 31 of each year to the commissioner on activities of the committee during the previous calendar year. Such reports shall include:

1. A description of each human research project reviewed and approved or disapproved;

2. Any significant deviations from proposals as approved;

3. A list of committee members, their qualifications for service on the committee, and their institutional affiliation; and

4. A copy of the minutes of any committee meetings conducted.

C. The chairman of the committee shall report as soon as possible to the commissioner any violation of the research protocol which led the committee to either suspend or terminate the research.

D. The commissioner may inspect the records of the committee.

E. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects conducted by any component of the department as annually reported to the commissioner by the committee.

2.2 For Institutions or Agencies Funded or Licensed by the Department

A. Prior to the initiation of a human research project by any institution or agency funded or licensed by the department, a description of the proposed human research project shall be submitted to a research review committee for review and approval. The description shall include a statement of the purpose of the proposed project and justification thereof, the criteria for inclusion of a participant in the research project, a description of what will be done to the participants, and a copy of the informed consent statement.

B. When more than one such institution or agency is involved in a research project, the cooperating entities may enter into joint review.

C. Such institutions or agencies having a committee shall report by January 31 of each year to the commissioner on activities of the committee during the previous calendar year. Such reports shall include:

1. A description of each human research project reviewed and approved or disapproved;

2. Any significant deviations from proposals as approved;

3. A list of committee members, their qualifications for service on the committee, and their institutional affiliation; and

4. A copy of the minutes of any committee meetings conducted.

D. The chairman of the committee shall report as soon as possible to the head of such institution or agency and to the commissioner any violation of the research protocol which led the committee to either suspend or terminate the research.

E. The commissioner may inspect the records of the committee.

F. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects conducted by such institutions or agencies as annually reported to the commissioner by the relevant research review committees.

PART III. THE RESEARCH REVIEW COMMITTEE

3.1 Composition

A. Each committee shall have at least seven members, appointed by the head of the institution, with varying backgrounds to provide complete and adequate review of activities commonly conducted by the institution. The committee shall be sufficiently qualified through the maturity, experience, and diversity of its members, including consideration of race, gender and cultural background, to promote respect for its advice and counsel in safeguarding the rights and welfare of participants in human research. In addition to possessing the professional competence necessary to review specific activities, the committee shall be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. If a committee regularly reviews research that has an impact on patients or residents within an institution as defined herein or other vulnerable category of participants, the committee shall have in its membership one or more individuals who are primarily concerned with the welfare of these participants and who have appropriate experience to serve in that capacity.

B. No committee shall consist entirely of members of one profession, and at least one member must be an individual whose primary concerns are in nonscientific areas (e.g., lawyers, ethicists, members of the clergy).

C. Each committee shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

D. No member of a committee shall participate in the committee's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the committee. The committee has responsibility for determining whether a member has a conflicting interest. The committee size shall be maintained at no fewer than seven persons by appointment of a substitute representative for each member with a conflicting interest.

E. A committee may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the committee. These individuals may not vote with the committee.

F. A quorum of the committee shall consist of a majority of its members including at least one member whose primary concerns are in nonscientific areas.

G. The committee and the institution shall establish procedures and rules of operation necessary to fulfill the requirements of this chapter.

3.2 Elements of the Committee Review Process

A. No human research shall be conducted or authorized by the institution or agency unless a research

review committee has reviewed and approved the proposed human research project giving consideration to:

1. The necessity and utility of the research;

2. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research;

3. The degree of the risk, and, if the research is nontherapeutic, whether it presents greater than minimal risk;

4. Whether the rights and welfare of the participants are adequately protected;

5. Whether the risks to the participants are outweighed by the potential benefits of the research to them;

6. Whether the voluntary informed consent is to be obtained by methods that are adequate and appropriate to the individual's educational level and language of greatest fluency;

7. Whether the written consent form is adequate and appropriate in both content and wording for the particular research and for the particular participants of the research relative to their educational level and language of greatest fluency and whether the consent document reasonably reflects full explanation and adequate understanding;

8. Whether the persons proposing to supervise or conduct the particular human research are appropriately competent and qualified; and

9. Whether criteria for selection of participants are equitable, especially in research regarding the future development of mental or physical illness.

B. The committee shall consider research proposals within 45 days after submission to the committee. In order for the research to be approved, it shall receive the approval of a majority of those members present at a meeting in which a quorum exists. A committee shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure committee approval.

C. During the committee review of research projects, no personal identifiers of present or potential participants should be stated.

D. The committee shall approve or develop a written description of the procedure to be followed when a participant has a complaint about a research project in which he is participating or has participated.

E. Any participant who has a complaint about a research project in which he is participating or has participated shall be referred to the committee to determine if there has been a violation of the protocol.

F. The committee shall require reports from approved research projects at least annually to ensure conformity with the approved proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. The committee shall also require a report from the research project at the conclusion of the project.

3.3 Expedited Review

A. The committee is authorized to conduct an expedited review of a human research project which involves no more than minimal risk to the subjects if:

1. Another institution's or agency's human research review committee has reviewed and approved the project; or

2. The review involves only minor changes in previously approved research and the changes occur during the approved project period.

B. Each committee which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

3.4 Informed Consent

A. To conduct human research, informed consent of the participant or his legally authorized representative must be obtained, subscribed to in writing by the participant or his legally authorized representative and supported by the signature of a witness not involved in the conduct of research, except as provided for in subsections F and H of this section. If the participant is a minor otherwise capable of rendering informed consent, consent shall be subscribed to in writing by both the minor and his legally authorized representative.

B. A legally authorized representative may not consent to nontherapeutic research unless it is determined by the committee that such research will present no more than a minor increase over minimal risk to the participant.

C. An investigator shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that assures absence of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative with regard to his educational level and language of greatest fluency.

D. No informed consent form shall include any language through which the prospective participant waives or appears to waive any of his legal rights, including any release of any individual, institution or agency or any agents thereof from liability for negligence.

E. Notwithstanding consent by a legally authorized representative, no person who is otherwise capable of rendering informed consent shall be forced to participate in any human research. In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed

consent shall not constitute the use of force.

F. The committee may approve a consent procedure which omits or alters some or all of the elements of informed consent set forth in 12VAC5-20-10, or waives the requirement to obtain informed consent provided the committee finds and documents that:

1. The research involves no more than minimal risk to the participants;

2. The omission, alteration or waiver will not adversely affect the rights and welfare of the participants;

3. The research could not practicably be performed without the omission, alteration or waiver; and

4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

G. Except as provided in subsection H of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by 12VAC5-20-10. This form may be read to the participant or the participant's legally authorized representative, but, in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed and witnessed; or

2. A short form written consent document stating that the elements of informed consent required by 12VAC5-20-10 has been presented orally to the participant or the participant's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the committee shall approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary and a copy of the short form shall be given to the participant or the representative.

H. The committee may waive the requirement that the investigator obtain written informed consent for some or all participants if it finds that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he wants documentation linking him to the research, and the participant's wishes shall govern. In cases where the documentation requirement is waived, the committee may require the investigator to provide participants with a written statement explaining the research.

3.5 Categories of Human Research Exempt from Regulation

Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from this chapter:

A. The surveillance and investigation by the department into all preventable diseases and epidemics in the Commonwealth and into the means for the prevention of such diseases and epidemics conducted

pursuant to §32.1-39 of the Code of Virginia.

B. Research designed to study on a large scale anonymous vital records and registry data collected pursuant to the Code of Virginia, Chapter 7 (§32.1-249 et seq.) of Title 32.1 (Vital Records), §32.1-64.1 (Virginia Hearing Impairment Identification and Monitoring System), §32.1-69.1 (Viginia Congenital Anomalies Reporting and Education System), §32.1-70 (Statewide Cancer Registry), §32.1-71.l (Statewide Alzheimer's Disease and Related Disorders Registry), and §§32.116.1 and 32.116.1:2 (Emergency Medical Services Patient Care Information System).

C. Research or student learning outcomes assessment conducted in educational settings such as research involving:

1. Regular or special education instructional strategies; or

2. The effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods; or

3. The use of educational tests, whether cognitive, diagnostic, aptitude, or achievement, if the data from such tests are recorded in a manner so that participants cannot be identified, directly or through identifiers linked to the participants.

D. Research involving survey or interview procedures unless responses are recorded in such a manner that the participants can be identified, directly or through identifiers linked to the participants, and either:

1. The participant's responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to his financial standing, employability, or reputation; or

2. The research deals with sensitive aspects of the participant's own behavior such as sexual behavior, drug or alcohol use, or illegal conduct.

E. Research involving survey or interview procedures, when the respondents are elected or appointed public officials or candidates for public office.

F. Research involving solely the observation of public behavior, including observation by participants, unless observations are recorded in such a manner that the participants can be identified, directly or through identifiers linked to the participants, and either:

1. The observations recorded about the individual, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to his financial standing, employability, or reputation; or

2. The research deals with sensitive aspects of the participant's own behavior, such as sexual behavior, drug or alcohol use, or illegal conduct.

G. Research involving the collection or study of existing data, documents, records, or pathological specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner so that participants cannot be identified, directly or through identifiers linked to the participants.

3.6 Committee records

A. Documentation of committee activities shall be prepared and maintained and shall include the following:

1. Copies of all research proposals reviewed, scientific evaluations that may accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants;

2. Minutes of committee meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the committee; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution;

3. Records of continuing review activities;

4. Copies of all correspondence between the committee and the investigators;

5. A list of committee members;

6. Written procedures for the committee; and

7. Statements of significant new findings provided to participants.

B. The records required by this chapter shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized employees or agents of the department at reasonable times and in a reasonable manner.

PART IV. APPLICABILITY OF FEDERAL POLICIES

Human research at institutions which are subject to policies and regulations for the protection of human participants promulgated by any agency of the federal government shall be exempt from these regulations. Such institutions shall notify the commissioner annually by January 31 of their compliance with the policies and regulations of federal agencies. The commissioner shall identify institutions exempt from this chapter as reported in accordance with this section in the annual report to the Governor and the General Assembly.

APPENDIX C:

SAMPLE CONSENT FORM

INSTITUTION NAME
STUDY NAME - CONSENT FORM

You have been invited to participate in a research study of (BRIEF EXPLANATION OF PURPOSE OF THE RESEARCH). This study is being conducted by (LIST ANY COLLABORATORS IN THE RESEARCH WHO WILL HAVE ACCESS TO STUDY DATA).

1. You will be asked to (DESCRIBE PROCEDURES/PROTOCOLS TO BE FOLLOWED; IDENTIFY ANY PROCEDURES WHICH ARE EXPERIMENTAL; DISCLOSE ALTERNATIVE PROCEDURES THAT MAY BE ADVANTAGEOUS TO THE SUBJECT; AND IF APPROPRIATE, STATE EXPECTED DURATION OF SUBJECT=S PARTICIPATION, APPROXIMATE NUMBER OF SUBJECTS, ANY COSTS OR COMPENSATION TO THE SUBJECT, AND ANY CIRCUMSTANCES UNDER WHICH THE SUBJECT'S PARTICIPATION MAY BE TERMINATED).

2. Your participation in this study is completely voluntary and you are free to discontinue participation at any time. Refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled. (WHERE APPLICABLE, DISCLOSE ANY CONSEQUENCES OF DECISIONS TO WITHDRAW FROM THE STUDY AND PROCEDURES FOR ORDERLY TERMINATION).

3. DESCRIPTION OF EXTENT TO WHICH CONFIDENTIALITY WILL BE MAINTAINED, INCLUDING HOW RECORDS WILL BE STORED, WHETHER ACCESS TO RECORDS WILL BE RESTRICTED, AND THAT IF NAMES OR OTHER IDENTIFYING INFORMATION WILL BE USED IN PUBLISHED REPORTS, WRITTEN PERMISSION WILL BE OBTAINED.

4. DESCRIPTION OF BENEFITS TO SUBJECT OR TO OTHERS, AND IF APPROPRIATE A STATEMENT THAT SIGNIFICANT NEW FINDINGS DEVELOPED DURING THE COURSE OF THE RESEARCH WHICH MAY RELATE TO THE SUBJECT'S WILLINGNESS TO PARTICIPATE WILL BE PROVIDED TO THE SUBJECT.

5. DESCRIPTION OF PSYCHOLOGICAL OR PHYSICAL RISKS OR DISCOMFORTS TO SUBJECT, OR STATEMENT THAT THERE ARE NO SUCH RISKS. FOR RESEARCH INVOLVING MORE THAN MINIMAL RISK, EXPLAIN WHAT WILL BE DONE IF INJURY OCCURS.

6. If you have any questions about the study, you may contact (NAMES), (TELEPHONE NUMBERS).

Your signature indicates that you read, understood, and had the opportunity to discuss the information provided above, and that you now agree to participate.

(SIGNATURE)

(DATE)

(SIGNATURE OF RESEARCH STAFF WHO ADMINISTERED INFORMED CONSENT).

APPENDIX D:

REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT INVOLVING HUMAN SUBJECTS

Virginia Department of Health
Office of Health Policy and Planning//Institutional Review Board
109 Governor Street, 10th Floor East; PO Box 2448
Richmond, VA 23218-2448

STATE USE ONLY
ID #:
Date Rec'd:
Expedited ☐
Full ☐

REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT INVOLVING HUMAN SUBJECTS

Submit either 1 electronic copy to the chair of the VDH IRB OR 7 hard copies (Full Board) or 2 hard copies (Expedited Review) of this completed form along with the protocol and other supporting documents to the Office of Health Policy and Planning/Institutional Review Board at the above address.

Title of Protocol	
Name and Title of Principal Investigator	Email Address
Name of Institution	Telephone Number
Address	
Name and Title of Department of Health Collaborator, if included in study and different from Principal Investigator	Email Address
Address	Telephone Number

Proposed Dates for Project

Beginning: _____ Ending:

Assurance of Confidentiality

1. The undersigned hereby agrees to the following terms and conditions related to a request for approval for research:
2. No data will be published or released in any form if a particular individual supplying the information or described in it is identifiable without the written permission of the subject(s) involved.
3. The identifying information will be used only for statistical purposes in medical and health research.
4. The identifying information will not be used as a basis for legal, administrative, or other actions which may directly affect those particular individuals as a result of their specific identification in this project.
5. The identifying information will be used only for the study or project proposed and the purposes described in the attached document. Use of the information for a research project other than the one described will not be undertaken until after a separate request is made to the Virginia Department of Health.
6. While identifiers still appear, access to paper, hardware and software will be secured. Paper records will be kept in locked cabinets and computers will be kept locked or have password protection.
7. All statements made to the Virginia Department of Health are correct.

Signature of Principal Investigator	Date
Name of Requester, if different from Investigator (Print)	Title
Signature of Requestor	

REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT INVOLVING HUMAN SUBJECTS
(Continued)

STATE USE ONLY
ID #:

1. Name(s) of any other IRBs reviewing this project.

2. Summarize the study protocol or project activities (attach a copy of the full protocol to this request for reference). Indicate specifically the way data will be collected and used.

3. List the potential risks to study participants.

4. List any potential benefits to study participants and/or to society.

5. Do your subjects include any of the following:

   a. Pregnant women or children (persons who have not attained the legal age for consent to treatments or procedures involved in the research)?

   ☐ Yes ☐ No

   b. Institutionalized mentally infirm people?

   ☐ Yes ☐ No

   c. Inmates/Prisoners?

   ☐ Yes ☐ No

   Since these subjects - and others like them who are either not competent or not free to give their own consent - are particularly vulnerable to coercion and undue influence, investigators must incorporate safeguards in the research plan, and be certain to document fully their informed consent or the informed consent of their legal representatives.

REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT INVOLVING HUMAN SUBJECTS
(Continued)

STATE USE ONLY
ID #:

6. Informed consent must be obtained from the subjects or, in the case of children, the parent or legal guardian. Do you intend to use an informed consent form?

☐ Yes ☐ No

If yes, please enclose a copy of the form, which should include all of the elements mentioned in the sample found in Appendix C. ALL SUBJECTS MUST BE TOLD AND UNDERSTAND THAT THEY CAN DECLINE PARTICIPATION IN THE RESEARCH. If you DO NOT intend to use a consent form, please explain your reasons here:

7. In what form and to whom will the results of your study or activities be released?

8. Describe how your organization will store and maintain the confidentiality of the identifying information.

9. Describe the disposition of identifying information (method and intended time frame).

10. Please provide any other information that would be helpful to the IRB.

APPENDIX E:

CONTINUATION REVIEW

Virginia Department of Health
Office of Health Policy and Planning/Institutional Review Board
109 Governor Street; 10th Floor East
PO Box 2448
Richmond, VA 23218-2448

CONTINUATION REVIEW

This form is to be completed and submitted to the above address only for studies that have been reviewed previously.

Title of Study or Project	ID No.
Name of Principal Investigator	E-mail Address
Address	Telephone No.
Name of Department of Health Collaborator, if included in study and different from Principal Investigator:	E-mail Address
Address	Telephone No.

Complete **EITHER** Section I or Section II.

Section I - This study does NOT require re-review because:

- ☐ It is no longer in progress.
- ☐ It was never started.
- ☐ It was recently re-reviewed on (date) ____ ____ / ____ ____ / ____ ____.
- ☐ Other (Specify):

_____

Section II - For studies that required re-review.

1. How many subjects have been entered into the study?

2. Have you received or are you aware of any adverse events or unanticipated problems involving risks to subjects or others, including breach of confidentiality, withdrawal of study subjects, or complaints about the study?

   ☐ Yes ☐ No

   If Yes, please explain:

3. Summarize here any recent literature, findings, or other relevant information, especially information about risks associated with the research, that study subjects should be aware of.

Have study subjects been informed of these findings?

☐ Yes ☐ No

If No, why not?

4. Have there been any changes in the informed consent forms?

☐ Yes ☐ No

If Yes, please submit a copy of the revised forms.

5. Have there been any significant changes from the original protocol?

☐ Yes ☐ No

If Yes, please describe:

Signature of Principal Investigator	Date

APPENDIX F:

REQUEST FOR EXEMPTION FROM IRB REVIEW

Virginia Department of Health
Office of Health Policy and Planning/Institutional Review Board
109 Governor Street, 10th Floor East
PO Box 2448
Richmond, VA 23218-2448

REQUEST FOR EXEMPTION FROM IRB REVIEW

Instructions: Submit 1 electronic OR 2 hard copies of this completed form along with cover letter, protocol, letters and other materials that will go to study subjects, and questionnaires to the Office of Health Policy at the above address.

Title of Study or Project	ID No.
Name of Principal Investigator	E-mail Address
Address	Telephone No.
Name of Department of Health Collaborator, if included in study and different from Principal Investigator:	E-mail Address
Address	Telephone No.

I (or we) request that the project named above be approved as exempt from review by the Institutional Review Board based on the following exemption criteria (see pages 7 – 9):

Signature of Principal Investigator: _____ Date: _____